DURATION OF HOSPITAL STAY POST – DISCHARGE AND ASSOCIATED FACTORS IN CHILDREN WITH MALIGNANCIES AGE 0 – 14 YEARS AT KENYATTA NATIONAL HOSPITAL

BY

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DECLARATION

I certify that this dissertation is my original work and has not been presented for the award of a degree in any other university.

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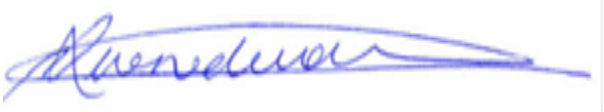

Signature _____ Date 9th July, 2021

DEDICATION

This work is dedicated to my wife Beth and my son Troy Richards for their support and patience. To my parents Habil Ogolla and Queens Ogolla who endeavoured to educate me in my formative years.

To the children with cancers especially at KNH without whom this study would not have been conducted.

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ABBREVIATIONS

ALL	Acute lymphoblastic leukemia
AML	Acute myeloid leukemia
CDC	Centre for Disease Control and Prevention
CLL	Chronic lymphoblastic leukemia
CML	Chronic myeloid leukemia
CT Scan	Computed tomography scan
GLOBOCAN	Global Burden of Cancer Study
HAIs	Hospital Acquired Infections
IARC	International Agency for Research on Cancer
IQR	Interquartile Range
JOOTRH	Jaramogi Oginga Odinga Teaching and Referral Hospital
KNH	Kenyatta National Hospital
KNH-UoN ERC	Kenyatta National Hospital-University of Nairobi Ethics Review Committee
MTRH	Moi Teaching and Referral Hospital
NHIF	National Health Insurance Fund
NHL	Non-Hodgkin lymphoma
UHC	Universal Health Coverage
UTI	Urinary Tract Infection
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Post-discharge hospital stay – Period when a patient is clinically allowed to leave a hospital with a documentation of discharge after a medical treatment by the doctor but still remains within the hospital facility due to reasons within or beyond the patient such as inability to clear the hospital bills, abandonment by caregivers.

Hospital Acquired Infection – Any new onset of symptoms after 48 hours of admission that is not related to the initial complaint that led to admission. For this study we relied on clinical symptoms for making the diagnosis. This was obtained from the file as indicated by the clinicians who managed the patient.

Table 1: Hospital Acquired Infections

Surgical site infection	**Any purulent discharge, abscess or spreading cellulitis at the surgical site.**
Sepsis	Documented or suspected infection plus ≥2 of SIRS criteria • Axillary temperature of 38.5C or < 36 C • Tachypnea >50/min (2-11months) or >40b/min (1-5years) >20b/min (>5 years) • White cell count, >12x10^9 or <4x10^9 or > 10% immature white cells • Blood glucose > 7.7 mmol/l in non-diabetes. • New altered level of consciousness.
Respiratory infection	Respiratory symptoms of cough, tachypnea >50/min (2-11months) or >40b/min (1-5years) >20b/min (>5 years) and Grunting with any documented x ray findings
Gastrointestinal system	Gastroenteritis symptoms of vomiting, diarrhea, abdominal pain and distensions

Central nervous systems	Complications will include complaints of convulsion, Projectile vomiting, motor weakness and altered level of consciousness.
Integumentary system	Symptoms includes Rashes, pruritus, ulcers and blisters
Genitourinary system	Symptoms include Dysuria, urethral discharges and lower back pain when passing urine plus at least positive urine dip stick test (nitrite or > 1+ leucocytes).
Vascular catheter infection	Inflammation, lymphangitis or purulent discharge at the insertion site.

Adapted from researchgate.net

Malignancy - Uncontrolled growth and spread of cells to other organs.

Waiver – Discretion that releases one from payment of a bill.

Metastasis – Ability of cancer cells to spread from one organ to another.

User fees - Are payments made by patients either from pocket or by insurance for health care services.

A child – Any person age 0-18 years. In this study we use age 0-14 years because children above 14 years at KNH are admitted to adults' wards and are treated using adult's oncology protocol.

ABSTRACT

Introduction

Cancer is a major cause of mortality and morbidity worldwide. World Health Organization (WHO) estimated that 9.6 million people died from cancer in 2018(1). Most paediatric cancers are managed with chemotherapeutic drugs combined with surgery and sometimes radiotherapy. These treatment modalities require frequent and long durations of hospitalization making cancer management quite expensive (2). This imposes a great financial burden especially among people in developing countries lacking health insurance. As a result, many who are discharged fail to exit hospital, adding to the financial burden and putting them at more risk of Hospital Acquired Infections (HAIs) (3).

Study justification

The study aims to quantity the burden, factors contributing to and complications associated with post discharge hospital stay in children with malignancies. Findings from this study may influence formulations of policies regarding discharges and advocacy for health insurance for children with malignancies in line with current policy on Universal Health Coverage (UHC).

Objectives of the Study

The objectives of this study were to determine the duration of hospital stay post- discharge in children with malignancies age 0-14 years at KNH and in a sub-analysis to describe the factors associated with this duration of Hospital stay post-discharge.

Study Methodology

The study was a Cross-sectional Retrospective Chart review among children age 0-14 years with malignancies treated at KNH between July 2019 and June 2020 and was conducted at KNH medical records department. Only those who had histological diagnosis were included in this study using consecutive sampling.

Results

A total of 192 files reviewed and analyzed. The duration of hospital stay post-discharge ranged from 1 day to 42 days. The median (IQR) duration of hospital stay post-discharge was 12 days (1-28 days). The duration of hospital admission ranged from 1 month to 9 months, with the median

(IQR) being 4 months (3-5 months). The average duration of hospital stay post-discharge of children whose caregiver did not have an active insurance at the time of admission was 14.38 days more than that of children whose caregivers had an active insurance (β =14.38; 95% CI: 11.30-17.45). The mean duration of hospital stay post-discharge among children with haematological cancers was 4.02 days more than that of children with solid cancers (β =4.02; 95% CI: 1.28-6.75). 18.7% of the children acquired infections during hospital stay post-discharge. 7.3% of the children in this study received a waiver of their hospital bill.

Conclusion

Duration of Hospital stay post-post discharge ranged from 1- 42 days. Having health insurance at admission, solid cancers and shorter duration of hospital admission were associated with reduction in hospital stay post-discharge, with subsequent reduction of patient exposure for more HAIs and waiver cases.

CHAPTER ONE: BACKGROUND OF THE STUDY

1.1 Hospital stay post discharge

Cancer is a major cause of mortality and morbidity worldwide. World Health Organization (WHO) estimated that 9.6 million people died from cancer in 2018. Out of the 9.6 million 400000 were children (1). Most paediatric cancers are managed with chemotherapeutic drugs combined with surgery and sometimes radiotherapy. These treatment modalities require frequent and long durations of hospitalization making cancer management quite expensive (2). This imposes a great financial burden especially among people in developing countries lacking health insurance. As a result, many who are discharged fail to exit hospital and remain as 'discharge in' adding to the financial burden and putting them at more risk of Hospital Acquired Infections (3). Once patients are managed as in-patients, they get discharged so that they can complete treatments at home and resume their normal daily duties.

Hospital stay post discharge is defined as the duration when a patient has been allowed to leave a hospital after medical treatment with a documentation of discharge but still remains within the hospital facility due to reasons within or beyond the patient`s control. Post discharge hospital stay has been used traditionally as a surrogate to evaluate healthcare efficiency, as well as hospital resource utilization(4). It has also been associated with increased mortality and other poor outcomes. It is a great problem mainly in developing countries. In Kenya, several debates in parliament have been brought forward on post discharges mainly in public hospitals and the plight of these patients highlighted in the media whenever there are crisis(5,6).

1.2 Factors contributing to hospital stay post discharge

Many from low socioeconomic background fail to exit the hospital once discharged. Many factors have been pointed out to contribute to this failed hospital exit. These factors include: Cost of treatment , abandonment of patient at the facility ,better services that may be provided at the hospital such as good meals, security and social interactions, traditional beliefs like pediatric cancers are a curse hence many caregivers may defer going home because they fear being blamed for the disease and health system delays(5).

1.2.1 Nature of the disease

The cost of cancer management is very high. This is due to its long duration of hospitalization, expensive procedures for making diagnosis and cost of treatment modalities(7,8). Childhood malignancies require long duration of hospitalization before children are discharged for subsequent management. The long duration of hospitalization depends on the stage of the disease at admission, the availability of equipment and skilled personnel for taking biopsy, the duration for analysis and report of biopsy results, availability of cancer medications and supportive products like blood and response of the disease to medication(9). Some of these delays are in critical components in care such as reporting biopsy specimens due to lack of adequate staff members.

1.2.2 Abandonment of patients

There is frequent abandonment of patients in government referrals hospitals and user fees are levied. Some of these patients are brought to these facilities by either police or good Samaritans while others are abandoned by their care givers during the course of treatment(10). These patients therefore fail to exit hospital mainly due to lack of their care givers to process their discharges and take them home. To mitigate this, hospitals are also mandated to have clear guidelines on how to discharge and continuous managements of patients even after discharge.

1.2.3 Goods and Services offered in hospitals

Some patients from developing countries fail to exit hospital after discharge due to the services rendered at the hospital. Goods and Services like food, shelter, clothing and security are assured once a patient is admitted. These services attract those who are destitute and cannot afford these basic needs at home(5). They therefore find it convenient to stay longer in hospital even after being discharge.

1.2.4 Traditional beliefs

Some traditions which base their beliefs on witchcraft may influence one from exiting hospital once discharge. Paediatric cancer particularly in some communities is believed to be caused by witchcrafts. Care givers from such community may have it difficulty to cope with the society after their children have been discharged home. Some of these parents may decide not to leave the hospitals after getting discharge until full recovery or completion of treatments(11)

CHAPTER TWO: LITERATURE REVIEW

Overview

Hospital stay post discharge is mainly a problem in developing countries. Minimal data exists on duration, associated factors and complications of post discharge hospital stay especially in paediatric oncology.

2.1 Factors contributing to post discharge stay

Many factors have been implicated to contribute to post discharge hospital-stay. These factors are summarized as follows:

a) High cost of treatment with associated lack of health insurance

b) Health System delay.

c) Abandonment of patient at the facility hence no relative to take the patient home after discharge.

d) Better services that may be provided at the hospital as compared to home such as good meals, security and social interactions

e) Social factors like traditions and beliefs.

f) Malignancies discharged for palliation. Many caregivers may defer going home with critical patients whose management requires only palliation.

A cross section descriptive study done at KNH in 2010 looked into factors contributing to hospital stay post discharge (5). This study enrolled 186 patients in the adult general ward. The study found out that many of the post discharge hospital stay was due to lack of finance with associated lack of health insurance. Only 4.8% had health insurance, 44% lacked social support that is to say they felt excluded and developed stigma. The nature of illness also contributed to post discharge stay especially chronic illness that were more likely to stay longer.

2.2 Long duration of hospitalizations from cancer treatment and its impact

Before 1980s, the health system in Kenya was from government budgetary allocation. However, in 1989 the government introduced user charges for the health services. In 1990 the user fee for out-patients were abolished but were reintroduced in 1992 due to health budgetary constraints(12**).** This user fees have made the cost of hospitalization very expensive causing many to fail to exit

hospital after discharge due to accrued bills. Cancer is a very expensive disease to manage. This cost ranges from diagnosis, chemotherapeutic drugs, radiotherapy, follow up test and follow up visits. Many from resource limited countries lose patients from failed or abandonment of treatment due to lack of funds (10).

Longer duration of hospitalization has direct effect on the cost of managements. This cost affects the patient, hospital and total health budget at large. Many patients in the developing world are poor and therefore they tend to seek medical care very late. Cancer management depends on staging and therefore late stage leads to poor outcomes. Cancer as a disease requires long duration of hospitalization and high cost of treatment that may make a patient unable to exit hospital when discharged. A study done in Netherlands showed that those who stayed in hospital for 5.1 days experienced adverse events with increased cost of £2600. The cost for those who suffered adverse events was £300million and nationally this translated to 1.3% of National hospital care budget (13).

Another study done in United States looked on the duration of hospitalization and probability of acquiring infection (3). They found out that increasing duration of hospitalization by one day increases the chances of acquiring infections by 1.37% and increasing length of stay by an average of 9.32 days. Another study done in Mexico looked into the risk factors associated with prolonged duration of hospitalization. This was a retrospective study done over 18 years (14). They found out that hematological malignancy was the most common cause of long duration of hospitalization. In surgery, small intestine surgical procedure had the longest duration of hospitalization and most patients who overstayed in hospital were those from low social economic backgrounds.

A prospective study done for over 8 months in United States looked into hospital induced complications (15). One thousand patients were enrolled. Hospital induced complications included: reaction to therapeutic drugs, reaction to diagnostic procedures, hospital acquired infections and reaction to blood transfusions. Results were, 20% had suffered hospital induced complications with 4 recorded deaths. Due to these complications duration of hospitalization was prolonged further in 9% and this further increased the risks of complication by 5%.

A systemic review of hospital stay in United State hospitals 2016 looked into the average length of hospitalization (16). It found out that the average length of hospital stay was 4.5 days this translated to an average of $10,400 that was a great problem to the low social economic people.

Another study done in Japan was about the influence of length of stay and patients satisfaction with hospital care (17). This was a cross-sectional study of 77 hospitals with 1050 patients enrolled and analyzed. The study found out that skill of nursing care, recovery of physical health, respect to the patients, short duration of hospital stay, doctors' clinical competence and good hospital reputation led to good patient satisfaction.

2.3 Prevalence of hospital acquired infections in paediatric oncology

Hospital acquired infection is any symptom after 48 hours of admission that was not related to the initial complaints that led to admission. Despite advances in paediatric oncology care, infections remain a major cause of morbidity and mortality among patients(18). Paediatric oncology patients have the highest risk for HAIs this is attributable to cancer itself being immunosuppressive, neutropenic from chemotherapeutic drugs, stem cell or bone marrow transplant, radiotherapy, several radiological investigations like x rays, CT scans and long duration of hospitalization(19). Management of HAIs proves very difficult. Many of these HAIs are multidrug resistant therefore their management becomes a public health concern thus more costs accrue. Significant paediatric oncological patients die from these infections(20).

Hospital acquired infection (HAIs) has been a global problem but worse in developing countries(21)**.** The management is mainly via standardized surveillance. Many hospitals in the developing world lack surveillance and do not have the capacity for microbiology tests hence limited data are available.

In cancer patients these HAIs are associated with more serious outcomes than those in the general ward. In fact, the prevalence in oncology patients is higher with poorer outcomes. Many oncology patients are faced with higher risk for acquiring these infections. These patients are usually immunosuppressed from neutropenia due to chemotherapeutic drugs and radiotherapy. A retrospective study done in South Africa on children with cancer in 2018 showed the prevalence of HAIs in paediatric oncology as 74%. 14% had complications with a case fatality of 2%(20). In this study 13.8% of the total blood samples taken yielded positive cultures. Of this, 49.1% had

gram negative bacterial infections while 41.6% yielded gram positive bacterial infections. A study done 2016 in Mexico cancer referral center in the oncology ICU showed prevalence of HAIs was at 40.7%. This was a prospective study done over 18 months. The mean duration for acquisition of HAIs was 7 days(22).

A study done in Greece in Haemato-Oncology Unit showed that risk for HAIs is higher in cancer patients compared to general patients. Findings were: 18.8% acquired 20 different HAIs with a crude mortality of 12.5% as compared to 2.9% crude mortality for patients without HAIs (18). Another study done in India 2015 Vikram hospital looked into prevalence of nosocomial infections in paediatric cancer patient (19). They found out that the prevalence of these nosocomial infections was at 86.6% with gram negative bacteria being isolated in 60.25% and gram positive bacteria in 39.75%.

In the general hospital wards, World Health Organization reported on the burden of endemic Hospital Acquired Infections and came out with the following findings. The prevalence of HAIs in developed countries ranges from 5.9%-9.3% with pooled prevalence of 7.6%. In developing countries the prevalence of HAI is 5.9%-19.1% with a pooled prevalence of 10.1%(23).

In US the prevalence of HAIs is between 4-6%. This study showed that clostridium difficile was the most common organism causing HAIs. A study in Greece showed that the prevalence of HAIs was at 9.1% with Urinary tract infection (UTI) topping the list. In Singapore the prevalence of HAI was 11.9% with Staphylococcus aureus topping the list. In South East Asia this prevalence was 9.1% with P. aeruginosa topping the causative agent while Iran the prevalence is 9.4% with UTI being the highest HAI(24).

2.4 Effects of having health Insurance on the outcome of cancer patients

The Kenyan Government through an act of parliament in 1967 established National Hospital Insurance Fund (NHIF). The aim was to provide accessible, affordable, and sustainable quality health service for all Kenyan Citizens. Currently only 7, 657,463 are principal members of NHIF with over 25 million dependents(2018) and this is way far below the Universal Health Coverage (UHC) expectation(26).

There are more than 22 other private health insurance companies in Kenya and each insurance company operates on its conditions and regulations(27). Health insurance has been studied widely and is now known to reduce the duration of hospitalization especially when it comes to payments of hospital bills. In the United States of America, Medicaid and Medicare are the main health insurances and having them is a matter of life and death for those diagnosed with lymphomas(28)

Having an active health insurance at point of diagnosis has been attributed to good outcome in the field of oncology. Many paediatric cancers have no specific presentation hence many are diagnosed very late. Patients from low economic areas will delay to seek medical attention due to lack of finances. Since these symptoms are non- specific, many diagnostic tests are required to make a conclusive diagnosis. Many of these tests are very expensive and require insurance. Those lacking health insurance therefore have poor health seeking behaviours. They also fail to buy the recommended chemotherapeutic drugs for the same. Some are forced to abandon treatment hence mortality remains high.

A retrospective study done in 2017 in Moi Teaching and Referral Hospital (MTRH) on patients who had NHL between 2010-2012 showed that 73% lacked insurance at the time of diagnosis. Many abandoned treatments at 44%. Five-year event free period for those who had insurance was 53%. A total 5-year survival rate was 29%. This study concluded that outcome of NHL in Kenya is poorer compared to developed countries (29).

Another study done in Kenya looked into survival rate of Wilms tumour. This was a retrospective study via cancer registry data. 133 files were included. They found out that the 2-year survival rate in Kenya was 52.7% compared to 90% in developed countries (30). The main reason for low survival rate in Kenya was loss to follow up and subsequent treatment abandonment. Those who had NHIF insurance tended to complete treatment with better outcome.

A retrospective study done in United States via cancer registry looked into the impact of health insurance on cancer patients. 364,507 patients' files were recruited. They found out that those patients from disadvantaged communities were more likely to present with distant metastatic cancer and there were less likely to receive cancer directed surgery. This study concluded that patients from disadvantaged communities benefit more from health insurance (28).

2.5 Psychosocial complications of cancer patients

Cancer as a disease, long duration of hospitalization for its management and hospital bills may make caregivers develop stress eventually leads to depression. Many caregivers have suffered this, especially when the patient dies from cancer. A cross-section study done at KNH recruited 62 parents of children with ALL. This study looked into association between socioeconomic status and psychological experience of parents with children on treatment for ALL. The result showed that many care givers suffered anxiety, shock and fatigue. The study concluded that financial challenge was a major cause of these psychological complications seen among caregivers (26).

2.6 Health system delay

Delayed discharge is an important problem for health-care providers internationally. It is defined as the period of continued hospital stay after a patient is deemed medically fit to leave hospital but is unable to do so for non-medical reasons(31). Patients may fail to exit hospital immediately after discharge because of system delays. Such system delays may include process of billing. Many hospital experience system failures like power break outs and systems delay logging for those hospitals using software for discharge process. In teaching and referral hospitals the doctors who are taking care of the patients may fail to write the official discharges in time since some may be involved in class work at that time.

These patients remains at a high risk for economic and public health problems(14). Age, type of disease may determine the normal duration of hospitalization. Acute condition tends to be treated faster and discharged while chronic conditions tend to take a longer duration of hospitalization. However some hospitals have been found to increase the length of hospitalization for their financial gain at the expense of patients(32). Once this happens patients find it quite hard to exit the hospital after discharged.

Table 2: Examples of literature review Studies on influence of health insurance

Author, setting and title	**Sample size**	**Study design**	**Population**	**Indicators of interest**	**Findings**
Gabriel et al 2010(5) Factors contributing to post discharge hospital stay KNH	N=186	cross – sectional descriptive study	General medical wards patients	Insurance status, Economic status, Nature of disease Waiver status	Findings were 95.2% Lack of NHIF, 44% lacked social support. The nature of disease also had an influence in post discharge hospital stay; Those who had chronic diseases tended to have more post discharge hospital stay as compared to the ones who had acute conditions.
Martijn et al 2017 (29) Influence of Health insurance on Paediatric NHL treatment in Kenya. MTRH	N=63	Retrospective study	Paediatric oncology	Insurance status, Sociodemographic characteristics, Survival rate, Relapse rate	Event free survival =29% 35% abandon treatment 22% had relapse 73% lacked insurance 27% had insurance this had event free of 53%

Table 3: Showing complications of hospital admissions

Mvala et al 2018(20) Blood stream infections in paediatric oncology patients. Red cross war memorial hospital S.A	N=89	Retrospective study	Paediatric Oncology	Microbiology findings from the infections, outcomes	Findings were prevalence of blood stream infections were at 74% with 14% complications and case fatality of 12%
Goyal et al 2015 (19) Prevalence of Nosocomial Infections associated with Cancer patients Vikram Hospital India	N=90	Prospective study	General cancer patients	Prevalence, Microbiology characteristics, outcomes	Prevalence of HAIs was higher in cancer patient than other patients. Prevalence = 86.6% Gram Negative Bacteria leading at 60.25% Gram positive bacteria at 39.75%
Cornejo-Juarez et al 2016 (22)	N=157	Prospective study	General cancer patients	Incidence, Influence from different cancers	The incidence of HAIs was 46% but there was no difference

Hospital Acquired infection in oncological units ICU Mexico					between solid and haematological malignancies.
Okumu et al 2015 (26) Association between socioeconomic and psychological experience of parents with children on Leukemia treatment at KNH	N=62	Cross sectional study	Care givers of Children with malignancies	Sociodemographic, complications like depression, abandonments, trauma, anxiety	There was a significant association between percentage of income spent and psychosocial distress index. Trauma/shock and anxiety topped at 90% while hopelessness at 30%.

2.7 Conceptual Framework

The dependent variable in this study is duration of hospital stay post discharge and complications that arises from this post discharge hospital stay. While the independent variable will include factors that are associated with post discharge hospital stay these include socioeconomic factors, health insurance status, and the type of cancer.

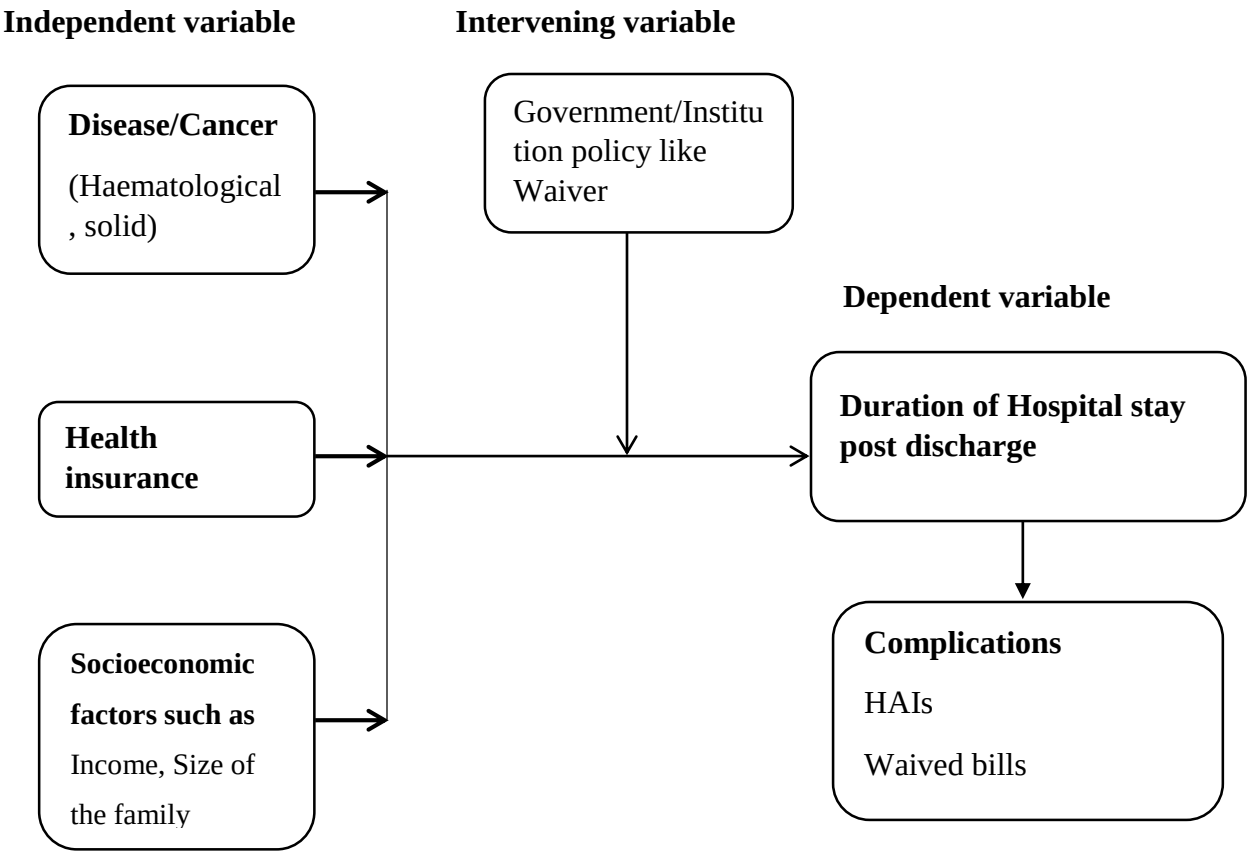

Figure 1: Conceptual framework

2.8 Study Justification

Cancer is a leading cause of morbidity and mortality among children. The five-year survival rate is estimated to be higher than 80% in developed countries as compared to 20% in low income countries. Because of the complicated and long duration of management of cancers, many patients fail to exit the hospitals in a timely manner following discharge. Reasons for this has not been determined in our setting but may relate to large bills, lack of health insurance, better relative services at the hospital compared to their homes and lack of social support. Those who fail to exit hospital after discharge may suffer consequences of prolonged hospital stay. These may include high risk of Hospital acquired infections, more accrued bills and psychosocial complications. Minimal studies have been done on duration of hospital stay post discharge, associated factors and complications in paediatric oncology. This study therefore will help us understand better the factors that make many children with cancers fail to exit hospital in a timely manner once discharged and associated complications. Findings from this study may give insight to KNH management and the ministry of health at large in formulating policies regarding discharges and

advocacy for health insurance for all in line with current policy on Universal Health Coverage (UHC).

2.9 Research Question

- What is the duration of hospital stay post- discharge, associated factors and complications in children with malignancies age 0-14 years at KNH?

2.10 Study Objectives

Primary objective

- To determine duration of hospital stay post-discharge among children age 0-14 years with malignancies at KNH.

Secondary Objectives

- To describe factors associated with hospital stay post-discharge in children with malignancies at KNH.
- To describe complications of hospital stay post-discharge among children with malignancies at KNH

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

The study was a Cross-sectional Retrospective Chart review among children with malignancies treated at KNH between July 2019 and June 2020. This was appropriate because children with malignancies are in many different ward at KNH that makes it difficult for a prospective study. The outcomes were multiple hence better with retrospective study.

3.2 Study site

This study was carried out at Kenyatta National Hospital Health Records and information department. which is the largest referral hospital in Kenya thus receiving referrals from all over the Nation, East and Central Africa. The hospital has a 2000 bed capacity hospital, with an average of 600000 outpatient visit and 70000 in patient annually. It is also a teaching hospital for University of Nairobi College of Health Sciences and Kenya Medical Training College. KNH engages in Research thus provide evidence based health care to the patient(33). Most cancer patients in Kenya are referred to KNH because it has most cancer specialized and advanced treatment modalities, making KNH appropriate site for this study. After a diagnosis is made via tissue biopsy the patient is transferred to either oncology unit or oncology room within paediatric wards where definitive management begins. These wards include 1E and general paediatric wards (special rooms for oncology). Patients taken for surgical interventions are brought back to the above wards for further oncological management.

The hospital has a fully-fledged records department that captures data on all patients admitted to the hospital using ICD 10 coding for the discharge diagnosis. The department receives oncology files from dedicated paediatric oncology ward (Ward 1E) and designated paediatric general wards.

3.3 Study population

Children who were admitted and managed at KNH in the period of July 2019 to June 2021 in their first admissions.

Inclusion criteria

Files of all patients with a diagnosis of malignancy aged 0-14 years in the period July, 2019 – June, 2020 at their fast admissions.

Exclusion criteria

Files with missing data on the duration of hospital stay post discharge were excluded from the study.

Files of patients with retinoblastoma were excluded since these children are treated entirely by ophthalmology services with total different protocol.

3.4 Sample size calculation

The sample size was determined by Cochran`s formula

$$n_0 = \frac{Z^2 pq}{e^2}$$

$$= \frac{(1.96)^2\ 0.453\ (1-0.5)}{(0.05)^2}$$

$$= \mathbf{385}$$

where: n = sample size

z = confidence interval (1.96) that corresponds to standard normal deviation

p = (0.5) proportion of the population with attribute in question since there were no previous studies on duration of hospital stay.

q = 1-p

e = Desired level of precision (margin of error)

Total population of children with malignancies within the period of July 2019 to June 2020 was 380. Considering inclusion and exclusion criteria, the sample size was adjusted for finite population of 380 patients using Daniel's Formula:

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$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

$$= \frac{385}{1 + \frac{385 - 1}{380}}$$

$$= \mathbf{192}$$

3.5 Sampling technique

The sampling frame was constructed from a list of all the patients aged 0-14 years with a diagnosis of a malignant condition seen in the hospital between July 2019 and June 2020. This was constructed using admission and discharge data from the records department and the respective wards (1E, designated paediatrics general ward). Consecutive sampling was applied to select the participants for inclusion in the study since the total population for the study before inclusion and exclusion criterial and calculated (n) had a small margin.

3.6 Study procedure

The study was carried out at the records department of KNH by principal investigator and research assistant after ethical approval by KNH-UoN ethic and research committee. The study was a cross-sectional retrospective chart review among children with malignancies treated at KNH between July 2019 and June 2020 at their first admissions. Data were collected retrospectively from the patient's files using a data collection form to determine duration of hospital stay post discharge, its associated factors and to document any medical complications as well as additional financial burden on the caregivers and the hospital. The following data were extracted.

a) Hospital stay post discharge which was obtained by subtracting the date of discharge summary from the date of clearance and exit from the ward.

b) Insurance status obtained from the admission records available in the file.

c) Socioeconomic status obtained from the biodata of the caregiver.

d) Type of cancer obtained from the file.

e) Any HAIs during the Hospital stay post-discharge.

f) Waiver status obtained from the finance clearance record attached to the file.

3.7 Data management and analysis

Data was collected from the files using a data collection form. Data collected was entered onto an Excel spreadsheet then exported to R version 3.5.3 statistical software for analysis. To determine the factors associated with the duration of hospital stay post-discharge, multiple linear regression model was fit to the data. This model is used to assess the relationship between a continuous outcome and continuous and/or categorical covariates. In this study, the outcome was the duration of hospital stay post-discharge (days) while the predictors included: age of child, sex of child, region of residence, caregiver's occupation, child's diagnosis, ownership of active insurance at diagnosis, whether one received waiver, duration of admission, and whether child had complications during hospital stay post-discharge. The β-coefficient, the corresponding p-values and 95% confidence intervals were reported. Bivariate analysis was done first to determine the potential predictors to include in the multivariable model. Multiple linear regression was used to determine the adjusted effect of the covariates on the duration of hospital stay post-discharge. Categorical data was tabulated and summarized as proportion and percentages; continuous variables were reported as medians with interquartile ranges as appropriate

Table 4: Data analysis

Objectives	**Parameters to be assessed**	**Parameters calculated**
Duration of hospital stay post-discharge	Length of stay in days	Median with IQR and linear regression analysis.
Associated factors	Family economic factors, Health insurance status, type of cancer and duration of admission	Frequencies with proportions and linear regression analysis
Complications	HAIs and directs costs to the patient and hospital	Incidence, Median with IQR

3.8 Ethical considerations

As a retrospective study there was minimal risk to the patients except on confidentiality and privacy. Patient confidentiality and privacy was observed. Data were anonymized to remove identifying information. Study participants were identified using their unique study numbers and the principal investigator maintained a study log linking each participant to their unique study number to facilitate file retrieval and reference when needed. The password to the study log was only accessible to the principal investigator.

Data collection forms and other study documents were stored in a locked suite while the extracted electronic data was stored in a password protected computer with access granted only to the principal investigator and the study statistician.

CHAPTER FOUR: RESULTS

A total of 192 children with malignancies age 0-14 years treated between July 2019 and June 2020 at Kenyatta National Hospital were included in this study. A total of 235 eligible files were retrieved for the study. 28 files were excluded from the study due to lack of histological diagnosis of cancer. 15 files were further excluded from the study because the lacked the data on duration of hospital stay post discharge leaving a total of 192 files for analysis.

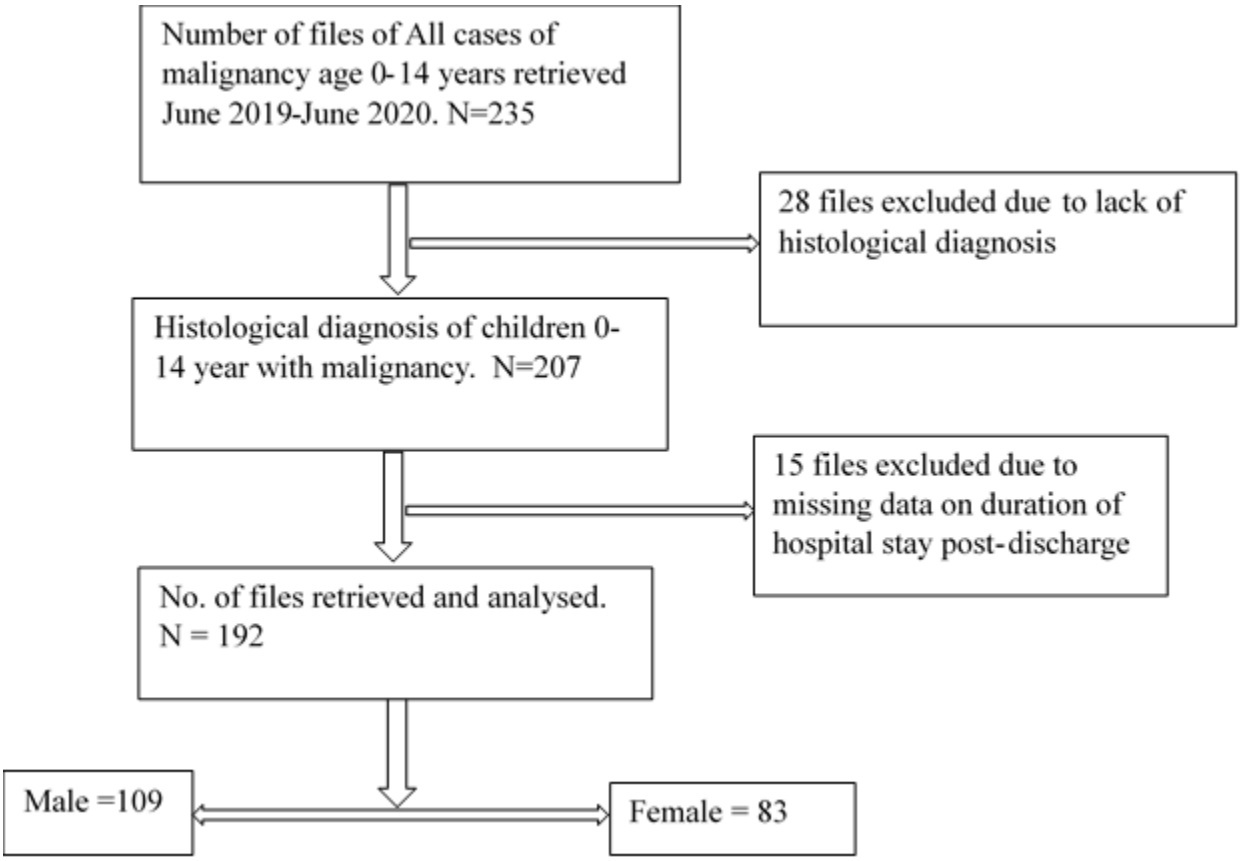

Figure 2: Showing how sample size was achieved

4.1 Socio-demographic information

The children were unevenly distributed across all the ages Figure 1. The median (IQR) age was 5.5 years (3-8 years) with the youngest being 1 year and the oldest being 14 years.

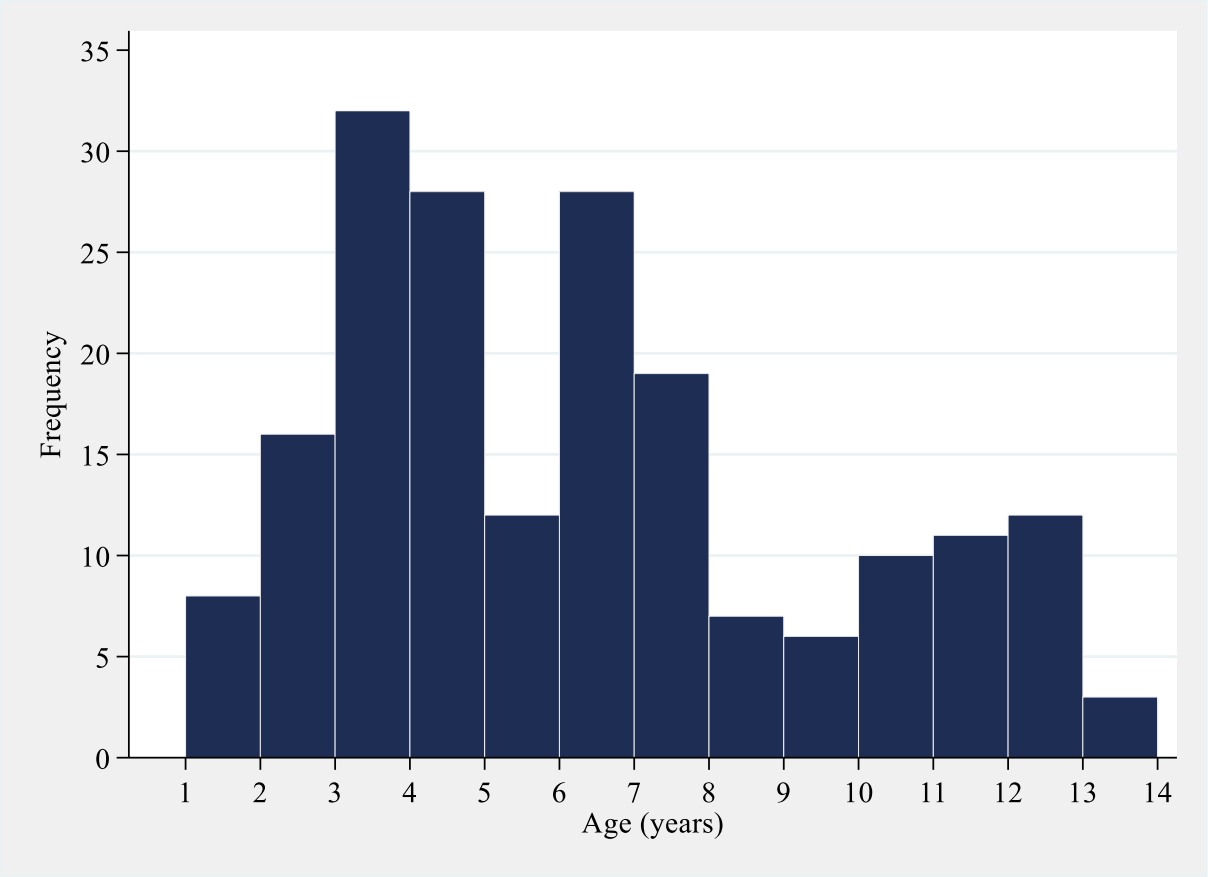

Figure 3: Distribution of age of children in the study (n=192)

More than half of the children in this study were males (56.8%). About two-thirds come from three regions closest to Kenyatta National Hospital (Central, Eastern and Rift valley) and a majority of the caregivers to the children (65.1%) were self-employed. Less than one-third (28.7%) had an active insurance at discharge. See Table 1 for more details.

Table 5: Socio-demographic and economic characteristics

Variable	Category	Frequency	Percent
Sex of child	Male	109	56.8
	Female	83	43.2
Region of residence	Central	45	23.4
	Eastern	43	22.4
	Rift valley	37	19.3
	Nairobi	32	16.7
	Nyanza	14	7.3
	Coast	10	5.2
	North Eastern	9	4.7
	Western	2	1.0
Occupation of caregiver	Self-employed	125	65.1
	Informal	47	24.5
	Formal/salaried	20	10.4
Have insurance at admission	No	128	66.7
	Yes	64	33.3
Have insurance at discharge	No	55	28.7
	Yes	137	71.3

4.2 Duration of hospital admission

The duration of hospital admission ranged from 1 month to 9 months, with a mode of 4-5 months (n=61 children). The median (IQR) duration of admission was 4 months (3-5 months).

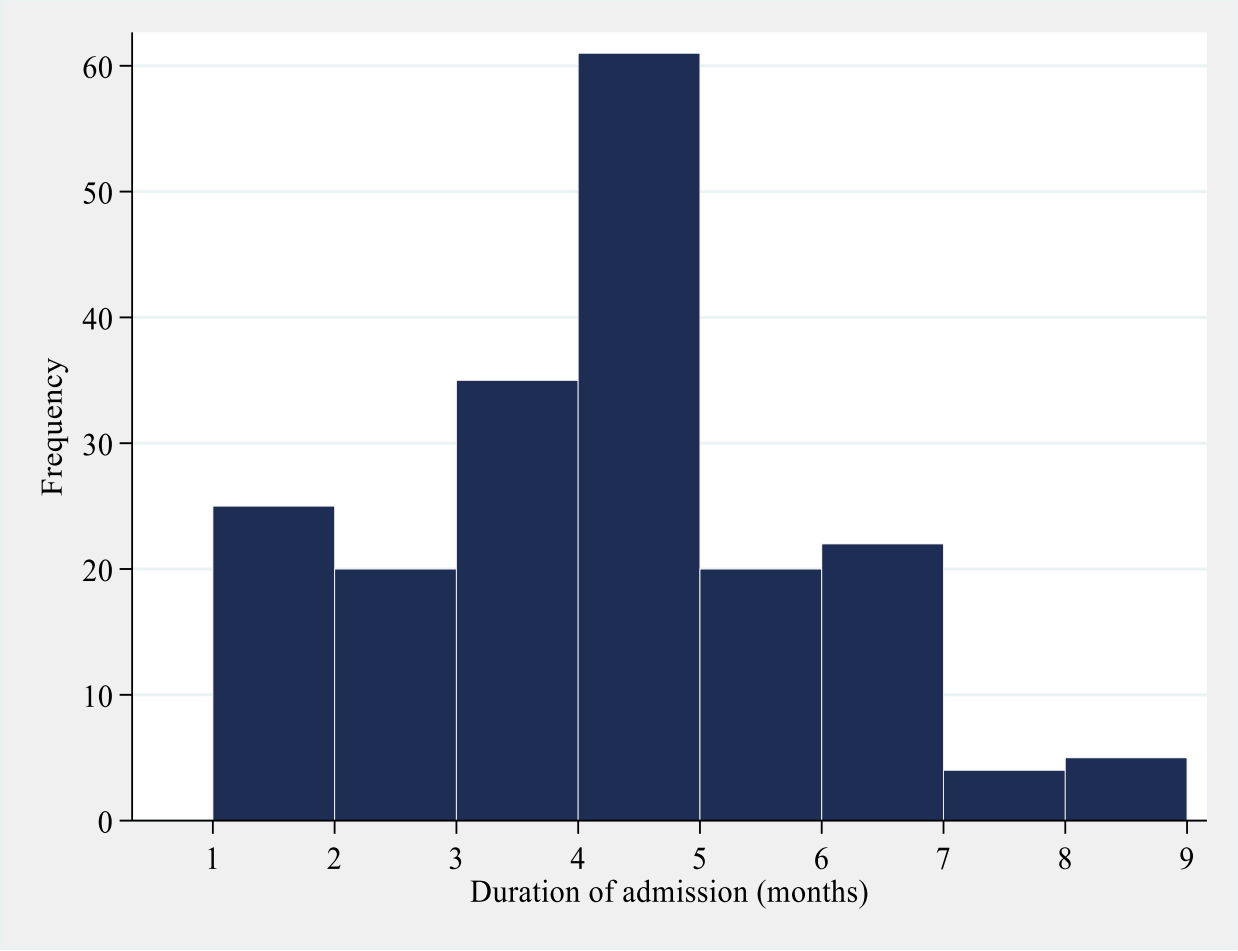

Figure 4: Distribution of the duration of hospital admission in months (n=192)

4.3 Duration of hospital stay post-discharge

The distribution of hospital stay post-discharge was bimodal (peaked at 0-3 days and at 27-30 days) and ranged from 1 day to 42 days (Figure 3). The median (IQR) duration of hospital stay post-discharge was 12 days (1-28 days). This means that if the children were ranked based on their duration of hospital stay post-discharge (either in descending or ascending order), then the middle 50% will have duration ranging between 1 and 28 days. The 1st peak was attributed to those who had health insurance at admission n = 64 and those who acquired health insurance immediately after admission allowing their insurance to mature at discharge n=13 however, the process of NHIF clearance took 1-2 days. 2nd peak n=60 was attributed to those who got registered late after admission and had to wait for their health insurance to mature which took 3-4 months.

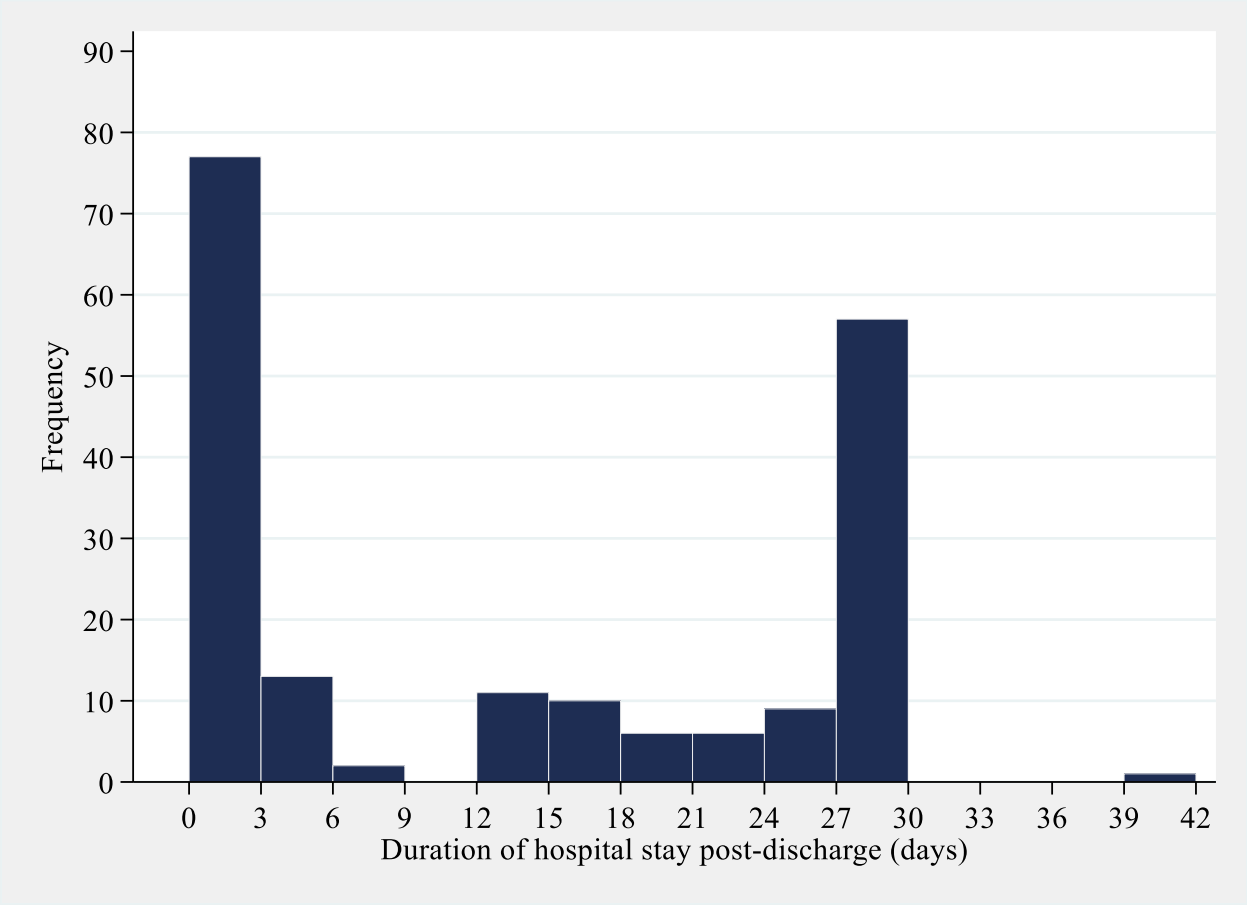

Figure 5: Distribution of hospital stay post-discharge (n=192)

4.4 Diagnosis

Most children were diagnosed with ALL (32.8%) followed by nephroblastoma (26.6%) and non-Hodgins lymphoma (15.1%). See Figure 4.

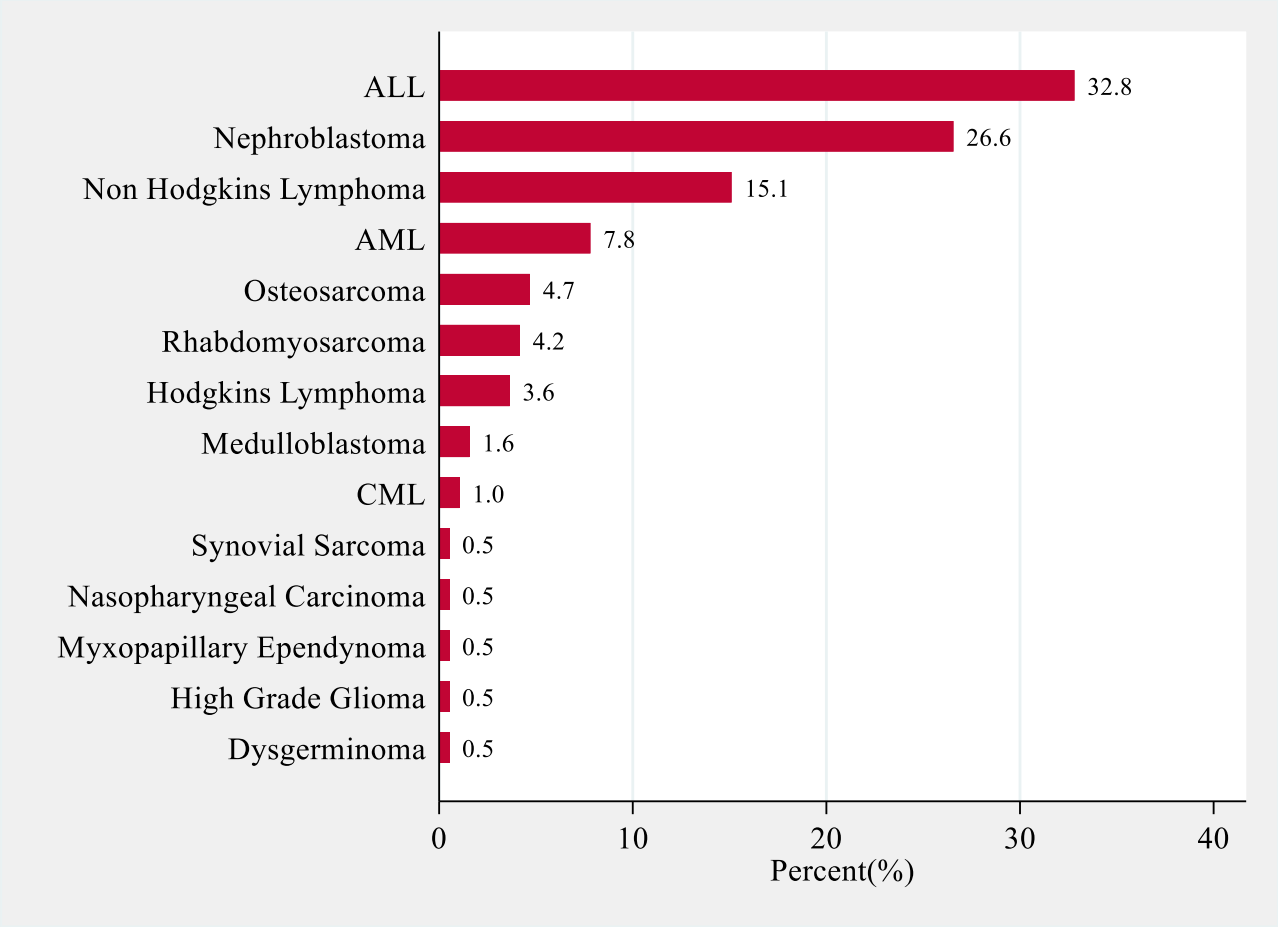

Figure 6: Diagnoses of the children (n=192; single response)

4.5 Documented complications suffered during post-hospital discharge stay

During hospital stay post-discharge, 18.7% of the children acquired infections during hospital stay post-discharge. One-tenth (10.9%) acquired sepsis while 5.7% acquired UTI. It is worth noting that out of the total 36 children who acquired infections, 26 children suffered more than one infection (multiple response), therefore, the sum of all the percentages do not necessarily add up to 100%.

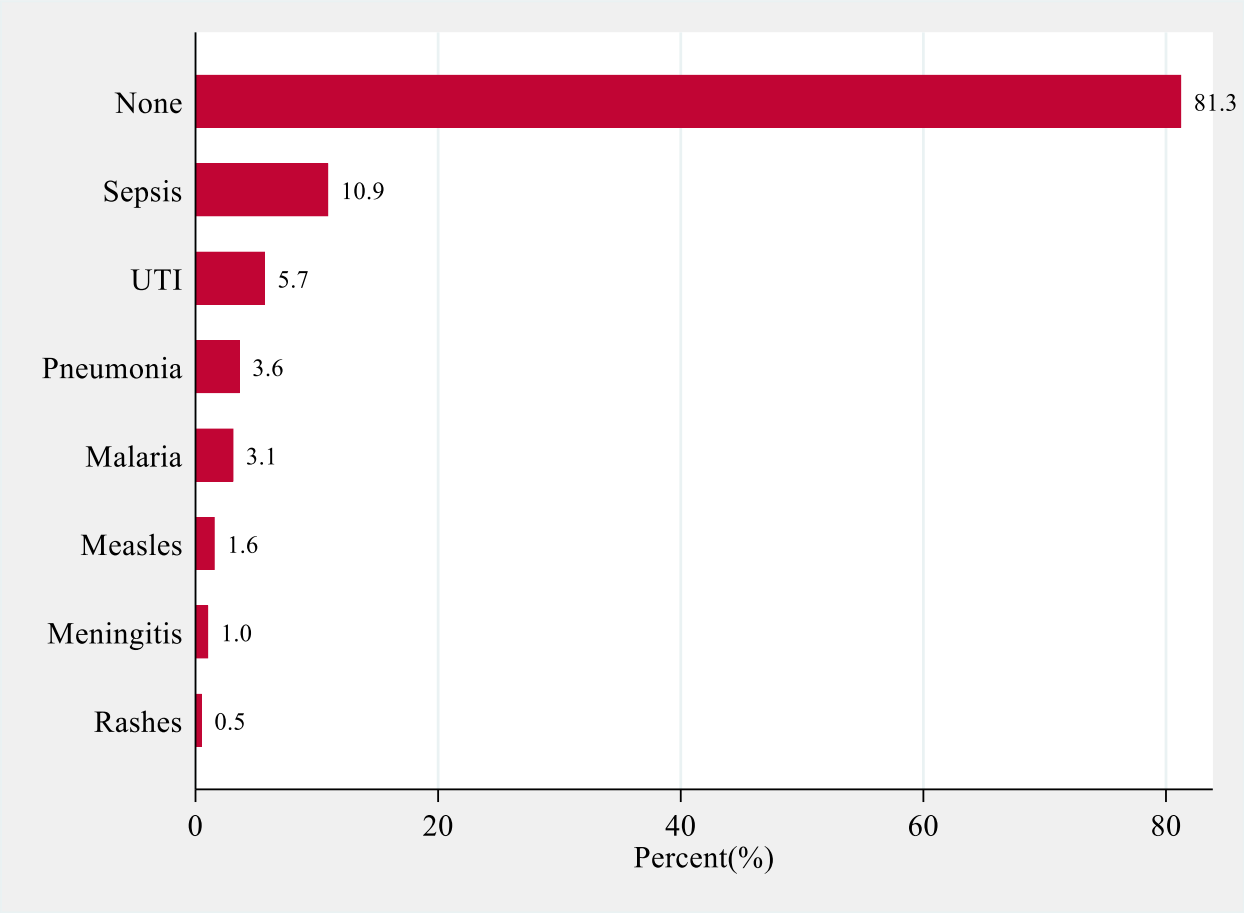

Figure 7: Complications/infections acquired during hospital stay post-discharge (n=192; multiple response)

4.6 Hospital bill waiver

Only 7.3% of the children in this study received a waiver of their hospital bill, the median (IQR) being approximately Ksh. 255,600 (158,047-274,345) with the total of Kshs. 2,552,860 waived.

Table 6: Hospital bill waiver

Variable	Category	Frequency	Percent
Received waiver	Yes	14	7.3
	No	178	92.7
Amount waived in Ksh. (n=14)	Median (IQR)	255,589 (158,047-274,345)	

4.7 Factors associated with post-discharge hospital stay

4.7.1 Bivariate analysis

Using a p value of 0.05 as statistically significant in this study, there were significant associations between duration of hospital stay post-discharge and diagnosis (p=0.001), ownership of active insurance at the time of diagnosis (p<0.001), duration of admission (p<0.001) and presence of acquired infections during hospital stay post-discharge (p<0.001). there was no significant association between duration of hospital stay post discharge and, Sex (p=0.110) region of residence (p=0.447) and occupation (p=0.688)

Table 7: Crude association of hospital stay post-discharge with covariates (predictors)

Variable (predictor)	Category	n(%)	β-coefficient	P-value
Age of child (years)	Mean(SD)	5.9(3.2)	0.47	0.083
Sex of child	Male	109(56.8)	-2.81	0.110
	Female	83(43.2)		
Region of residence	Central	45(23.4)	0.30	0.447
	Eastern	43(22.4)		
	Rift valley	37(19.3)		
	Nairobi	32(16.7)		
	Nyanza	14(7.3)		
	Coast	10(5.2)		
	North Eastern	9(4.7)		
	Western	2(1.0)		
Occupation of caregiver	Self employed	125(65.1)	0.41	0.688
	Informal	47(24.5)		
	Formal/salaried	20(10.4)		
Diagnosis (broad)	Solid cancers	112(58.3)	5.94	**0.001**
	Haematological cancers	80(41.7)		
Had active insurance at diagnosis	No	137(71.4)	-16.01	**<0.001**
	Yes	55(28.7)		
Received waiver	Yes	14(7.3)	-3.26	0.332
	No	178(92.7)		
Duration of admission (months)	Mean(SD)	3.7(1.7)	1.94	**<0.001**
Complications during hospital stay post-discharge	No	156(81.3)	9.49	**<0.001**
	Yes	36(18.7)		

Note: In this analysis, Haematologocal cancers referred to any of the following: ALL, AML or CML. Solid cancers referred to any of the following: Dysgerminoma, High grade glioma, Hodgkins lymphoma, Non-Hodgkins lymphoma, Medulloblastoma, Myxopapillary ependynoma, Nasopharyngeal carcinoma, Nephroblastoma, Osteosarcoma, Rhabdomyosarcoma or Synovial sarcoma

.

4.7.2 Multivariable analysis

With duration of hospital stay post-discharge as outcome of interest a step wise multivariate analysis was carried out. Child age, sex, diagnosis, and ownership of an active insurance at the time of diagnosis were significantly associated with the duration of hospital stay post-discharge (Table 4).

Controlling for other covariates in the model, the average number of days of hospital stay post-discharge increased by 0.53 day for every additional year in age (β =0.53; 95% CI: 0.12-0.94). This implies that on average, the older the child, the longer the hospital stay post-discharge.

Adjusting for other confounders in the model, the average duration of hospital stay post-discharge among males was 3.07 days more than that of females (β =3.07; 95% CI: 0.43-5.71). In other words, on average, males stayed in hospital post-discharge longer than females did.

After controlling for other predictors in the model, the mean duration of hospital stay post-discharge among children with haematological cancers was 4.02 days more than that of children with solid cancers (β =4.02; 95% CI: 1.28-6.75). Put another way, children with haematological cancers typically stayed longer in hospital post-discharge compared to those with solid cancers.

Adjusting for other factors in the model, the average duration of hospital stay post-discharge of children whose caregiver did not have an active insurance at the time of diagnosis was 14.38 days more than that of children whose caregivers had an active insurance (β =14.38; 95% CI: 11.30-17.45). This means that those who did not have an active insurance at diagnosis stayed longer at the hospital post-discharge compared to those who had.

Table 8: Adjusted association of hospital stay post-discharge with covariates (predictors)

Factors (predictors)		*β*-coefficient	P-value	95% C.I
Age of child (years)		0.53	**0.012**	0.12 - 0.94
Sex of child				
	Female	Reference		
	Male	3.07	**0.023**	0.43 - 5.71
Diagnosis (broad)				
	Solid cancers	Reference		
	Haematological cancers	4.02	**0.004**	1.28 - 6.75
Had active insurance at diagnosis				
	Yes	Reference		
	No	14.38	**<0.001**	11.30 - 17.45
Duration of admission (months)		Reference		
		0.74	0.063	-0.04 - 1.52
Complications during post-hospital discharge stay				
	No			
	Yes	2.78	0.134	-0.86 - 6.42

CHAPTER FIVE: DISCUSSIONS

The study was conducted retrospectively on 192 medical records of children with malignancies age 0-14 years who were treated at KNH between July 2019 to June 2020. The duration of hospital stay post-discharge ranged from 1 day to 42 days. The median (IQR) duration of hospital stay post-discharge was 12 days (1-28 days). There were limited data available on duration of hospital stay post-discharge as this is mainly a problem in the developing world. The distribution of hospital stay post-discharge was bimodal (peaked at 0-3 days and at 27-30 days). The first peak was attributed to the duration taken by NHIF for the clearance process. This included those who had insurance at admissions and those who got registered immediately after admission and therefore their insurance status was active at point of discharge. The second peak was attributed to three groups, those who got registered late for the insurance after admission and had to wait for the insurance to mature, those who had to struggle and pay from their pockets and those who eventually got waived. There were significant associations between duration of hospital stay post-discharge and ownership of health insurance at the time of admission, duration of admission and presence of acquired infections during hospital stay post-discharge. Only 33.3% had health insurance at the point of admission. This percentage however increased to 71.3% at the point of discharge. This shows an improvement to the study done by *Gabriel et al* 2010 (5) at KNH that showed that only 4.8% had insurance at admission. A retrospective study done in 2017 in Moi Teaching and Referral Hospital (MTRH) on patients who had NHL between 2010-2012 showed that 27% had insurance at the time of diagnosis (29). The increment in percentage for those possessing health insurance at admission from the studies of *Gabriel et al* 2010 and *Martijn et al* 2017 could be attributed to creation of awareness and advertisements on benefits of having active health insurance in Kenya (5,29). A further awareness given to all who are admitted especially in oncological words could explain the increment in percentage in possession on health insurance ad admission and at discharge.

HAIs rate was 18.7% for those who were waiting to be released from the Hospital after discharge. One-tenth (10.9%) acquired sepsis while 5.7% acquired UTI. This is much higher rate than study done by *Gupta et al* in North India in 2013 that showed HAIs rate of 9.4% for the paediatric oncology patients, 50% acquired blood stream infection, 36% acquired pneumonia and 14% UTI. Another study done by *Naveed et al* 2012 Pakistan that showed HAIs rate of 3.1% for the paediatric oncology. Blood stream infection was 90% and UTI at 2.9% (20). The higher percentage of HAIs in our study compared to Gupta et al 2013 and Naveed et al 2012 studies could be attributed to the following: the longer duration of hospitalizations that a rises from delays in making diagnosis and delays in

management, overcrowding in our words since KNH is the main referral hospital in the region and late identifications and managements of HAIs in our set up as compared to India and Pakistan

Most children were diagnosed with ALL (32.8%) followed by nephroblastoma (26.6%) and non-Hodgins lymphoma (15.1%). This was not in keeping with the study done by *Mwanda et al* 2000 that showed NHL being the most common diagnosed paediatric cancer in Kenya and another study by *Martijn et al* 2018 at MTRH showed that NHL is the most common diagnosed paediatric cancer in Kenya (29). However, these could be attributed to the presence of NHL treatment centres in western Kenya (JOOTRH and MTRH). NHL cases are high in the western part of Kenya and coastal region due to malaria endemicity and high HIV prevalence in those regions. Having treatment centres in western Kenya led to few referrals to Kenyatta national Hospital.

5.1 Conclusion

Duration of Hospital stay post-post discharge ranged from 1- 42 days. Having health insurance at admission, solid cancers and shorter duration of hospital admission were associated with reduction in hospital stay post-discharge, with subsequent reduction of patient exposure for more HAIs and waiver cases.

5.2 Recommendations

- All children with malignancy should get mandatory enrollment for Health insurance at admission.
- Further prospective study that would explain why some who had health insurance also had long hospital stay post discharge and other associated complications from hospital stay post-discharge like depression.

5.3 Limitation of this study

1. The study was a retrospective therefore we analyzed already available data. Documentation of the medical records was not up to standards and some important information were missing or not fully recorded.
2. Other complications from hospital stay post-discharge like depression, indirect cost to the patients could not be elucidated from this study.
3. This study did not include retinoblastoma which is fairly common in Kenya because its management is mainly by ophthalmologist with different protocols.

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APPENDICES

Appendix 1: Data collection form

1. **Demographic information**
   a. Identity code: ☐
   b. Age: ☐
   c. Sex: ☐
   d. Residence: ☐
2. **Diagnosis**: …….
3. **Socio-economic status**

   Occupation (caregiver): …..……..

4. Health Insurance status at point of admission

   (YES) ☐ (NO) ☐

   If **NO**, go to question **(5)**

   If **YES**, was it active at point of admission (YES) ☐ (NO) ☐

5. Type of insuarance**.....**
6. Hospital waiver offered (YES) ☐ (NO) ☐

   If **YES**, how much? .....

7. Duration of admission**.....**
8. Duration of post hospital discharge stay **…….....**
9. Documented complications suffered during post hospital discharge stay

……
……
……
……

10. Management modalities for hospital acquired infections post discharge

……

……

……

……....

11. Treatment outcomes

……

……

……

……

Researcher to check on details on managements and outcomes

Appendix 2: Ethical Approval

UNIVERSITY OF NAIROBI (UoN) COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
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KNH-UoN ERC
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Facebook: ttps://www.facebook.com/uonknh.erc
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KENYATTA NATIONAL HOSPITAL (KNH)
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

(To be submitted with Application for ERC Review of Research)

Exempt studies to be defined

KNH-UoN ERC

REQUEST FOR WAIVER OF INFORMED CONSENT

(Not Required for Exempt Studies)

Project Title: DURATION OF HOSPITAL STAY POST – DISCHARGE AND ASSOCIATED FACTORS IN CHILDREN WITH MALIGNANCIES AT KENYATTA NATIONAL HOSPITAL

Principal Investigator and Institutional affiliation: DR. DORN SUNDAY OGOLLA. UNIVERSITY OF NAIROBI, SCHOOL OF MEDICINE, DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH

Date: _____28/06/2020_____

Under special circumstances, investigators may request one of three types of waivers to obtaining written informed consent from research participants.

1. **Alteration of informed consent.**

With this waiver, the investigator may provide to the participants a consent which does not include or which alters one or all of the required elements. Examples of when this waiver might be applicable would be, when a researcher is conducting secondary data analysis and the participants cannot be located or when requiring informed consent might somehow actually have negative consequences for research participants.

2. **Waiver of parental permission**.

   This waiver would be used in cases where something may be legal for a child to do (i.e. contraception) without parental permission and obtaining parental permission would violate that privacy. An example of this type of waiver would be a survey on children (which would require parental permission) but the survey is about their experience on contraception usage.

3. **Waiver of written documentation** that informed consent was obtained. With this waiver, the investigator would be required to read or provide the informed consent form to a participant, but would not need to obtain the participant's signature on the consent form. Examples of when this waiver might be applicable would be some internet or phone surveys or when signing the form might have some negative consequence for the participant. It must be emphasized that these waivers will be given only when there are compelling reasons for doing so.

The Ethics and Research Committee determines which type of consent applies to your research, but please indicate the type that you are requesting.

☐ ✓**Waiver or alteration of the informed consent process.** *(Complete Section I)*

☐ **Request for waiver of parental permission.** *(Complete Section II)*

☐ **Waiver of written documentation of consent.** *(Complete Section III)*

I. Request for waiver or alteration of the consent process (Not required for Exempt studies)

I believe that this protocol is eligible for waiver or alteration of required elements of the informed consent process because the protocol meets all of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for the following :)

1. The research presents no more than "minimal risk" of harm to participants. _____

_____The study is a retrospective study hence and therefore will have no direct risk to the patient _____

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

__Data collection will be restricted to the principal investigator and research assistant to ensure confidentiality

_____

_____

3. The research could not practicably be carried out without the waiver or alteration.

_____ _____

_____ The parents or caregivers will not be available at the hospital and with the current movement restrictions this will not be possible. Documented contacts may also not be reachable due to other reasons like changed contacts._____

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

_____

_____ Participants will be reached in the events of unexpected relevant information is obtained during data collections.

_____

5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each:

_____

a) INTRODUCTION - Participants and their parents will not be readily available at time of conducting the study.

_____

b) PURPOSE OF THE STUDY - Lack of participant availability being a retrospective study.

_c) WHAT WILL BE DONE DURING THE STUDY –The study will involve use of patient records and will not require the participants' physical presence during the study.

d) RISKS, HARMS AND DISCOMFORTS ASSOCIATED – Besides invasion of privacy, the study has no other foreseeable risks, harms and discomforts. This will be addressed by restricting access to collected data and use of patient codes rather than names as well as entering data using a password protected computer.

e) STUDY BENEFITS- The study offers no direct benefit to the participants however information obtained will enhance future patient care.

f) COST TO PARTICIPANTS- There will be no cost to the participants during the study.

g) REIMBURSEMENT FOR PARTICIPANTS- No reimbursements will be made to participants.

f) FURTHER QUESTIONS- Participants will not be available to ask questions about the study.

g) PARTICIPANT CHOICES- Participants will not be accessible to make voluntary decision to take part in the study.

h) CONSENT FORM (STATEMENT OF CONSENT)- Parents will not be available to apprehend a signature of written informed consent for the study.

_____

6. The research does not involve non-viable neonates:

The the study is retrospective and thus will not involve non-viable neonates.

7. The research is not subject to FDA and/or national research regulation:

Retrospective study only hospital data will be used

II. Request for waiver of parental permission (Not required for Exempt studies)

I believe that this protocol is eligible for waiver of parental permission because the protocol meets all of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options :)

Option 1

1. The research presents no more than "minimal risk" of harm to participants.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each:

_____
_____

6. The research does not involve non-viable neonates:

_____
_____

7. The research is not subject to FDA and/or national research regulation:

_____
_____

Option 2:

1. The research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children)

_____

_____

2. An appropriate mechanism for protecting the children who will participate as participant in the research will be substituted

_____

_____

3. The research is not subject to FDA and/or national research regulation:

_____

_____

4. The waiver is consistent with international and national law:

_____

_____

III. Request for waiver of written documentation of consent (Not required for Exempt studies and not required when the consent process is waived.)

I believe that this protocol is eligible for a waiver of written documentation of informed consent because the protocol meets one of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options :) **(NOTE: Even when documentation of informed consent is waived, the investigator is required to give participants full consent information, and to obtain their voluntary consent orally.)**

Option 1

(Example: Conducting interviews with street children engaged in drug abuse. The only record of the name or other identifying information of the participants would be the signed consent form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm.)

Explain*:*

1. The only record linking the participant and the research would be the consent document.

_____
_____

2. The principle risk would be potential harm resulting from breach of confidentiality.

_____
_____

3. Each participant will be asked whether the subject wants documentation linking the participant with the research and the participant's wishes will govern.

_____
_____

4. The research is not subject to FDA and / national research regulation.

_____
_____

Option 2

(Example: Using an anonymous survey consent or conducting telephone interviews with politicians about how constitutional provision for funding of political parties will affecting the campaign process of smaller parties

1. The research presents no more than minimal risk of harm to participants.

_____

_____

2. The research involves no procedures for which written consent is normally required outside of the research context.

_____

_____

Approval (KNH-UoN ERC Chairperson: Check all that apply to indicate that the waiver or alteration is approved and to indicate agreement with the investigators protocol specific findings justifying the waiver.)

☐ Waiver or Alteration of the Consent Process

☐ Waiver of parental permission

☐ Waiver of Written Documentation of Consent

NOTE: To approve a waiver of written documentation of informed consent the investigator must provide a written document describing the information to be disclosed. This document has to include all required and appropriate additional elements of consent disclosure, unless the consent process has been altered.

Chose one of the following when approving a waiver of written documentation:

☐ The investigator must provide a written description of the information provided orally to the participant.

☐ The investigator does not have to provide a written description of the information provided orally to the participant.

APPROVED BY CHAIR KNH-UoN ERC:

Name: _____ Signature _____

Date and Stamp:_____

ETHICAL APPROVAL

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KENYATTA NATIONAL HOSPITAL APPROVED 10 JUL 2020 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Ref: KNH-ERC/A/209 10th July 2020

Dr. Dorn Sunday Ogolla

Reg. No. 1-158/11766/2018
Dept.of Paediatrics and Child Health

School of Medicine

College of Health Sciences

University of Nairobi

Dear Dr.Ogolla

RESEARCH PROPOSAL - DURATION OF HOSPITAL STAY POST. DISCHARGE AND ASSOCIATED FACTORS IN CHILDREN WITH MALIGNANCIES AT KENYATTA NATIONAL HOSPITAL (PI 56/0312020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- I-JON ERC) has reviewed and approved your above research proposal. The approval period is 10th July 2020 - 9th July 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.

c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- I-JON ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- IJoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewa0.
g. Submission of an executiue-s.unmau report within 90 days upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- IJoN ERC websitehttp://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M. L. CHINDIA

SECRETARY KNH.UoN ERC

c.c. The Principal, College of Health Sciences, UoN

The Director, CS, KNH

The Chairperson, KNH- I-JoN ERC

The Assistant Director, Health Information, KNH

The Dean, School of Medicine, (JON

The Chair, Dept. of Paediatrics and Child Health, I-JON

Supervisors: Dr. Lawrence Owino Okong'o, Dept.of Paediatrics and Child Health, UoN

Prof. Ruth Nduati, Dept. of Paediatrics and Child Health, UoN Dr. Grace Mbatia, Dept. of Paediatrics and Child Health, UoN

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Dr. Dorn Sunday Ogolla

Reg. No.H58/11766/ 2018

Dept.of Paediatrics and Child Health

School of Medicine

College of Health Sciences

University of Nairobi

8th June 2021

Dear Dr. Ogolla

Re: Approval of modifications*- study titled, 'Duration of Hospital stay post-discharge and associated factors in children with malignancies at Kenyatta National Hospital (P156/03/2020)

Refer to your communication dated 24th April 2021.

The KNH-UoN ERC has reviewed and approved the changes made to the study title and also the revisions made on the target population from children age 0-18 years to 0-14 years.

The study title has therefore changed from, "Duration of hospital stay post-discharge and associated factors in children with malignancies at Kenyatta National Hospital" to, "Duration of hospital stay post-discharge and associated factors in children with malignancies •age 0-14 years at Kenyatta National Hospital'.

It is noted that these changes will not cause any additional risk to the study participants, and will also not alter the study outcomes.

The revised proposal reflecting the changes is hereby approved.

Yours sincerely,

PROF. M. L. CHINDIA

SECRETARY. KNH-UON ERC

PRO

c.c. The Principal, College of Health Sciences, UoN

The Senior Director CS, KNH
The Chairperson, KNH-U0N ERC
The Dean, School of Medicine, UoN
The Chair, Dept. of Paediatrics and Child Health, UoN
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